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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/512,072	11/04/2004	Andrea Trombi	024931-00026	2437

4372 7590 10/18/2006

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EXAMINER

ALI, SHUMAYA B

ART UNIT PAPER NUMBER

3771

DATE MAILED: 10/18/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/512,072

Applicant(s)

TROMBI, ANDREA

Examiner

Shumaya B. Ali

Art Unit

3771

– The MAILING DATE of this communication appears on the cover sheet with the correspondence address –

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 7/21/06.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1 and 3-5 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1 and 3-5 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Status of Claims***

Claims 1,3-5 are pending in the current application.

### ***Response to Arguments***

Applicant's arguments, see remark, filed on 7/21/06, with respect to the rejection(s) of claim(s) 1,3-5 under the ground of nonstatutory obviousness-type double patenting have been fully considered, the terminal disclaimer filled to overcome the double patenting rejection is approved, however, upon further consideration, a new ground(s) of rejection is made in view of Blacker et al. US Patent No. 6,450,163 B1.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 4 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Limitation "reed-like" is vague. Applicant is respectfully required to clarify what is considered "reed-like".

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

**Claims 1,2-5 are rejected under 35 U.S.C. 102(b) as being anticipated by Blacker et al. US Patent No. 6,450,163 B1.**

**As to claim 1, Blacker et al.** in a breath actuated nebulizer see figures 1-3 disclose an apparatus for nebulizing a liquid, in particular for aerosol therapy, the apparatus comprising: a nebulizing ampoule (14) provided with at least one opening (70) for aspirating and/or expelling air from/to the environment and with a mouthpiece (98) for dispensing a nebulisation of medical product; and a valve (60) for regulating a flow of air into an/or out of the ampoule said valve being positioned in correspondence with said at least one opening and comprising a shutter (62) able to move between an operative blocking configuration corresponding to an obstruction of said at least one opening and an operative configuration of consent to the passage of the flow of air (), a ring (52) connected to the shutter to anchor the shutter to a tubular portion of the

ampoule said tubular portion being positioned in correspondence with the at least one opening and a plurality of deformable connecting elements (84) between the ring and the shutter to allow said shutter to move from said operative blocking configuration to said operative configuration of consent and vice versa, said movement being directly caused by an inspiration and/or expiration phase by a user, the deformable elements are spiral shaped and have a first end fastened peripherally to the shutter and a second end fastened to the ring (co.4 lines 39-67, col.5 lines 1-40) .

**As to claim 3, Blacker et al.** disclose a holed protective element (56) positioned in correspondence with the at least one opening to prevent the introduction of foreign bodies into the ampoule.

**As to claim 4, Blacker et al.** additionally disclose a second shutter (100) to cover a first opening of the ampoule necessary to expel to the environment air exhaled by a user, said second shutter being a deformable reed-like body having an end fastened in correspondence with the first opening and an end that is free to move away from the first opening to uncover the first opening at least partially and allow the escape of air (see fig. 3, col.6 lines 61-64)

**As to claim 5, Blacker et al.** further disclose wherein the valve is associated with a supplementary channel (20) of the ampoule.

### *Conclusion*

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US Patents: US 6,929,003 B2 and 5,584,285 A are cited to teach valve used with nebulizer.

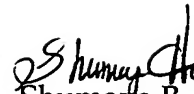
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shumaya B. Ali whose telephone number is 571-272-6088. The examiner can normally be reached on M-W-F 8:30am-8:30pm and Tu-Th 8:00am-1:00pm.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on 571-272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Art Unit: 3771

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 10/14/2006  
Shumaya B. Ali  
Examiner  
Art Unit 3771

  
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10/16/06